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| APPLICATION NO.            | FILING DATE                             | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------|---|----------------------|---------------------|------------------|
| 10/812,380                 | 03/29/2004                              | Iftikhar Khan        | 1800-000001         | 2606             |
| -                          | 7590 02/16/2007<br>CKEY & PIERCE, P.L.O | C.                   | EXAMINER            |                  |
| P.O. BOX 828               | 1111 1 0 3 41 40202                     |                      | DEAK, LESLIE R      |                  |
| BLOOMFIELD HILLS, MI 48303 |   |                      | ART UNIT            | PAPER NUMBER     |
|                            |   |                      | 3761                |                  |
|                            |   |                      |                     |                  |
| SHORTENED STATUTORY        | PERIOD OF RESPONSE                      | MAIL DATE            | DELIVERY MODE       |                  |
| 3 MON                      | THS                                     | 02/16/2007           | DADED               |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|  |  | Application No.   | Applicant(s)   |  |  |  |
|--|--|---|--|--|--|--|
|  |  | 10/812,380  | KHAN ET AL.  |  |  |  |
|  | Office Action Summary  | Examiner  | Art Unit   |  |  |  |
|  |  | Leslie R. Deak  | 3761   |  |  |  |
|  | The MAILING DATE of this communication appears on the cover sheet with the correspondence address<br>Period for Reply  |   |  |  |  |  |
| WHIC<br>- Exter<br>after<br>- If NO<br>- Failu<br>Any  | ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DATE is not of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. It is period for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | I. lely filed the mailing date of this communication. D (35 U.S.C. § 133). |  |  |  |
| Status   |  |   |  |  |  |  |
| 1)⊠  | Responsive to communication(s) filed on 11 De  | ecember 2006.   |  |  |  |  |
| 2a)⊠   | This action is <b>FINAL</b> . 2b) This action is non-final.  |   |  |  |  |  |
| 3)   | 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is   |   |  |  |  |  |
|  | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  |   |  |  |  |  |
| Dispositi  | on of Claims   |   | ·  |  |  |  |
| 4)🛛  | 4)⊠ Claim(s) <u>1-20</u> is/are pending in the application.  |   |  |  |  |  |
|  | 4a) Of the above claim(s) is/are withdrawn from consideration.   |   |  |  |  |  |
|  | 5) Claim(s) is/are allowed.  |   |  |  |  |  |
|  | Claim(s) <u>I-20</u> is/are rejected.  |   |  |  |  |  |
| •  | Claim(s) is/are objected to.   |   |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or election requirement.  |  |   |  |  |  |  |
| Applicati  | on Papers  |   |  |  |  |  |
| 9)[  | The specification is objected to by the Examine  | r.  |  |  |  |  |
| 10)⊠ The drawing(s) filed on <u>26 March 2004</u> is/are: a)⊠ accepted or b)⊡ objected to by the Examiner.   |  |   |  |  |  |  |
| ,  | Applicant may not request that any objection to the  |   |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. |  |   |  |  |  |  |
| Priority (   | under 35 U.S.C. § 119  |   |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:   |  |   |  |  |  |  |
| 1. Certified copies of the priority documents have been received.  |  |   |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No   |  |   |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage  |  |   |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.  |  |   |  |  |  |  |
|  | see the attached detailed Office action for a list   | or the certified copies not receive   | :a.  |  |  |  |
| Attachmen  | t(s)   |   |  |  |  |  |
|  | te of References Cited (PTO-892)   | 4) Interview Summary Paper No(s)/Mail D   |  |  |  |  |
| 3) Infor   | ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) er No(s)/Mail Date   | 5) Notice of Informal F 6) Other:   |  |  |  |  |

U.S. Patent and Trademark Office PTOL-326 (Rev. 08-06) SA

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#### **DETAILED ACTION**

## Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 2. Claims 1-3, 6, 7, 10, 11, 13, 15-17, 19, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2005/0203457 to Smego.

In the specification and figures, Smego discloses the apparatus and method as claimed by applicant. With regard to claims 1-3, 6, 7, 10, 11, Smego discloses an AV shunt 10 comprising an arterial graft 40 with a lead end anastomosed to the brachial artery, a venous outflow catheter 30 threaded through the jugular vein with an intake end deposited in the right atrium of the heart, and a cuff 20 wherein the cuff inlet connects to the arterial graft and the cuff outlet connects to the venous catheter, directing fluid therethrough (see FIGS 13, 19, paragraphs 0170-0175, 0184). The shunt is comprised of at least one flexible and biocompatible material, such as PTFE, polyethylene terephthalate, or polyurethane (see paragraphs 0054, 0126, 0132).

With regard to claims 13, 15, and 16, Smego discloses that the shunt apparatus may be used to provide vascular access for a hemodialysis apparatus (see paragraphs 0008-0009), connecting the jugular vein to the brachial artery (see FIG 19).

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With regard to claim 17, 19, and 20, Smego discloses the method of surgically implanting the shunt as claimed (see paragraphs 0164-0191), connecting the graft to a dialysis apparatus (see paragraph 0191), and allowing the dialysis apparatus to withdraw, filter, and return blood to the patient (see paragraphs 0008-0009).

## Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. Claims 4, 5, 8, 9, 12, 14, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2005/0203457 to Smego.

In the specification and figures, Smego discloses the device and method substantially as claimed by applicant with the exception of the specific catheter sizes claimed by applicant. Smego clearly discloses that the shunt may be manufactured in a variety of different linear lengths and interior and exterior diameter sizes (see paragraph 0121). Smego further suggests that the shunt comprises a size near the ranges claimed by applicant (see paragraph 0126). It has been held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. See MPEP 2144.04(IV)(A). It appears that the device and method

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disclosed by Smego would perform in the same manner as claimed by applicant.

Therefore, the sizes claimed by applicant are held by the examiner to be an obvious variation of the device and method disclosed by Smego.

# Response to Amendment/Arguments

- 5. Applicant's amendment and arguments dated 11 December 2006 have been entered and considered. Applicant's amendment to claim 7 has rendered moot the 35 USC 112, second paragraph rejection presented in the Office action mailed 11 September 2006. Accordingly, the rejection is withdrawn.
- 6. Applicant's arguments with respect to the pending claims have been considered but are most in view of the new ground(s) of rejection.

#### Conclusion

- 7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:
  - a. US 2005/0137614 Porter et al
    - System for connecting implanted conduits
- 8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patent Examiner
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7 February 2007

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TATYANA ZALUKAEVA SUPERVISORY PRIMARY EXAMINER